EXHIBIT A

WILLIAM MIXON, RPH

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I, William Mixon, RPh, MS, FIACP, FACA hereby submit the following expert report on behalf of Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic, a Professional Corporation, John W. Culclasure, MD, Debra Schamberg, RN, CNOR, and Vaughan A. Allen, MD.

My understanding is that additional information relevant to my opinion may be disclosed in the future, either through depositions or through the criminal trial of the individuals associated with NECC who have been indicted. Thus, I hereby reserve the right to amend this report.

I. Qualifications

I am licensed as a pharmacist in both Tennessee and North Carolina and was licensed as such in 2012.

I obtained a bachelor of science in pharmacy from the Medical University of South Carolina in 1977. I completed a hospital pharmacy residency at Spartanburg General Hospital (Spartanburg, SC) in 1981. And, I obtained my masters of science at the University of North Carolina (Chapel Hill, NC) in 1983, while completing another ASHP accredited hospital pharmacy residency program at UNC Hospital.

I have been an adjunct assistant professor University of North Carolina Eshelman School of Pharmacy, University of North Carolina (Chapel Hill) since 2010. From 1998 to the present, I have served as a preceptor at the University of North Carolina Eshelman School of Pharmacy (Chapel Hill). I have also served as a clinical associate professor of pharmacy practice at the Wingate University School of Pharmacy (Wingate, NC) since 2006. And, I have been a preceptor at the Campbell University

College of Pharmacy and Health Sciences (Buies Creek, NC) since 2004. In these academic roles, I have taught both sterile and nonsterile compounding for many years, which includes sterile compounding of injectable medications (including steroids) pursuant to USP <797>.

I have been retained by various compounding pharmacies and hospital pharmacy to consult regarding sterile and nonsterile compounding. I also serve on the Chapter <797> Subcommittee of the U. S. Pharmacopeial Convention Expert Committee for Compounding, and have done so since 2010.

Finally, since 2003, I have owned and managed The Compounding Pharmacy in Hickory, North Carolina, a PCAB-accredited, compounding-only pharmacy. My pharmacy has compounded a variety of sterile medications, including triamcinolone diacetate, an injectable steroid suspension. As a result, I am familiar with the standard of care applicable to both the compounding and sale of injectable steroids.

I have reviewed demographic information regarding Nashville, Davidson County, Tennessee. I have also personally visited Nashville. I believe Nashville to be a similar medical community to Hickory and Chapel Hill, North Carolina, where I practice. And, I believe the standard of care for the compounding and sale of medications in Nashville to be similar to the standard of care in Hickory and Chapel Hill, North Carolina. Thus, I believe I am competent to testify as to the standard of care applicable to Nashville, Davidson County, Tennessee.

II. Materials Considered in Forming Opinions

I have considered the following in forming my opinions: my education, training, experience, and the materials I have reviewed, which include the following:

1. FDA Form 483 to NECC
2. Mass. BoP Preliminary Investigation Report
3. NECC Indictment
4. Congressional Memo: "FDA's Oversight of NECC and Ameridose: A history of missed opportunities?"
5. Video from Inspections of NECC's Facility in December 2012 and July 2014
6. Video from NECC's Surveillance Cameras
7. NECC Environmental Monitoring Results
8. Audio and Video Excerpts from Barry Cadden's Training for Sales Personnel
9. NECC's Standard Operating Procedures
10. Logged Formula Worksheets for the Three Contaminated Lots of MPA
11. ARL Testing Results for the Three Contaminated Lots of MPA
12. Daily Fill Logs for the Three Contaminated Lots o MPA
13. Scientific Air Analysis Testing Results from 2011 and 2012
14. A Floorplan Showing the Layout of NECC's Facility
15. Monthly Cleaning Logs Completed by UniClean Technicians
16. Documents regarding a 2012 complaint to NECC from Massachusetts Ear and Eye Institute (the customer complaint, a letter from the Mass. BoP to NECC regarding the complaint, and NECC's response letter).

17. Joe Cabaleiro, RPh, *New England Compounding Center Indictment*, INT'L J. PHARM. COMPOUNDING, March-April 2015, at 94.
18. Transcript of Deposition of Steve O'Neil
19. Transcript of Deposition of Tommy Means of Analytical Research Laboratories (with exhibits 516-7, 516-8, 516-9, 516-10, 516-12, 516-17, 516-19, 516-24, 516-26, 516-27, 516-28, 516-29, 516-30, 516-31, 516-32, 516-33, 516-34, 516-35, 516-36, 516-40, 516-42, 516-44, 516-46, 516-47, 516-51, 516-58)
20. Transcript of Deposition of Edwin Cardona
21. Transcript of Deposition of Ricardo Dos Santos
22. Transcript of Deposition of Edgardo Camacho
23. Transcript of Deposition of Philip Austin, PhD
24. Information from an Interview of Joseph Connolly
25. USP <797>
26. USP <71>
27. USP <85>
28. FDA Form 483 to ARL
29. Second Amended Master Complaint
30. STOPNC, *et al.*'s Answer
31. Demographic information regarding Nashville, Tennessee – Attached as Exhibit 1.

I may use these materials as exhibits to support my opinions. All are either publicly-available to the Plaintiffs or have already been produced in this litigation with the exception of the items attached hereto as Exhibits (as indicated in the above list).

III. Summary of Factual Basis for Opinions

Based on my review of the materials described above, below is a narrative summary of the factual basis for my opinions. As alluded to at the outset of this report, the factual information regarding the goings on at NECC has been somewhat limited to date due to the criminal indictment and the unwillingness of former NECC employees to provide substantive testimony, rather than asserting their Fifth Amendment right against self-incrimination. I reserve the right to amend, supplement, or revise this report should it become necessary.

* * * * * * *

a. Brief History of NECC

Barry and Lisa Cadden opened NECC in 1998 at a facility in Framingham, MA owned by Ms. Cadden's family, the Conigliaros. Members of the Conigliaro family also had ownership interests in NECC. From the outset, NECC was a compounding pharmacy. According to Mr. Cadden, it was one of, if not the, first compounding-only pharmacies in the state of Massachusetts. Initially, NECC did not compound medications in a cleanroom, but sometime after its opening a cleanroom was constructed in NECC's space at the Framingham facility. Additional cleanrooms were added later.

In the early 2000s, the Conligliaros and Caddens opened another drug company in the Framingham facility called Ameridose. In 2006, Ameridose contracted with Liberty

Industries to construct a new cleanroom in the Framingham facility, and Liberty constructed another cleanroom in the Ameridose space in 2008. In 2011, Ameridose relocated to Westborough, MA, and, in June of 2011, NECC moved into Ameridose's old space in the Framingham facility and began using the 2006 and 2008 cleanrooms. The 2006 cleanroom, the larger of the two, became known as cleanroom 1, and the 2008 cleanroom became known as cleanroom 2. Prior to NECC's move, the space appears to have gone through some minor renovations. Before NECC began operating in the new space, it was inspected by the Massachusetts Board of Pharmacy in May of 2011.

b. Cleanroom and Compounding Process Generally

Sterile injectable steroids, including MPA, were compounded in cleanroom 1. Thus, this summary focuses on cleanroom 1, but it is my general understanding that cleanroom 2 operated in a similar manner. Pharmacist Glenn Chin supervised cleanroom 1 and personally participated in compounding sterile injectable steroids.

1. Pharmacy Technicians

Generally speaking, NECC grouped its pharmacy technicians into three categories: cleaning, compounding, and processing. Cleaning technicians often also served as processing technicians and vice versa. Compounding technicians, however, generally served only as compounding technicians, although they also performed some cleaning and processing functions at times (for example, the compounding technicians cleaned their work space between batches of medications).

Cleaning technicians, obviously, cleaned the cleanrooms. Cleanroom 1 was cleaned at the beginning of and end of each day in accordance with NECC's SOPs

regarding cleaning frequency. Logs were supposed to be completed documenting when different surfaces or equipment were cleaned and by whom. While the cleaning was always completed in a timely manner, technicians sometimes failed to complete the corresponding cleaning log. Mr. Chin instructed technicians to simply fill out the logs at the end of the month, whether the technician was the person who had actually done the cleaning or not. As noted above, compounding technicians also cleaned their workspace throughout the day between batches of medication.

Additionally, an outside company known as UniClean or UniFirst came into NECC's facility once a month before the facility opened for the day and completed the following cleaning tasks:

- Empty and wash all trash receptacles, replace liners, and remove to designated areas
- Vacuum floors with HEPA-filtered vacuums
- Clean and sanitize pass throughs
- Mop and sanitize floors with sterile IPA using UniClean's cleanroom mopping system
- Clean and sanitize walls with sterile IPA using UniClean's cleanroom mopping system
- Clean and sanitize ceilings with sterile IPA using UniClean's cleanroom mopping system
- Clean and sanitize exterior of hoods.

UniClean typically used 70% isopropyl alcohol when completing these tasks.

Joseph Connolly and Cory Fletcher were the only two compounding technicians in cleanroom 1. Compounding technicians, as the name implies, compounded the medication (*i.e.*, weighed out the ingredients and mixed them together). Mr. Fletcher is

the compounding technician who was responsible for compounding sterile injectable steroids. However, Mr. Chin also participated in compounding steroids. In fact, he refused to teach others how to use the homogenizer (a piece of equipment necessary for compounding injectable suspensions, like MPA), in order to protect his job security at NECC. Once medications were compounded, they were stored in pre-sterilized Nalgene bottles to await processing once NECC received orders.

Processing technicians working in the cleanrooms were responsible for filling, stoppering, and capping vials. A computer program in the cleanroom, referred to as "the compounder," alerted processing technicians to new orders that needed to be filled (including the type of medication and the number of vials). The processing technicians would then retrieve the Nalgene bottles with the appropriate medication and fill, stopper, and cap the vials. Once the vials were filled, stoppered, and capped, they were sent out to the warehouse for labeling and packaging by other processing technicians. Owen Finnegan and Steven Haynes were the two processing technicians in cleanroom 1 who filled, stoppered, and capped vials of injectable steroids.

2. Medication Testing

After compounding a sterile medication, NECC would draw two 5 mL samples **from the bulk preparation** to send to Analytical Research Laboratory ("ARL"), an independent laboratory, for sterility, endotoxin, and potency testing. Per USP <797>, which incorporates USP <71> by reference, sterility testing requires a sample to be incubated for 14 days, as well as lays out the minimum number and volume of samples to be tested depending on the total amount of the product compounded

When testing the medication, ARL's general procedure is as follows: A client orders the tests to be run through ARL's online submission form or via a hardcopy submission form and sends the actual sample to ARL. Once the sample is received, it is logged into ARL's system and brought to the testing lab. The laboratory personnel review the client's order form and perform the selected tests. Once the tests are completed, ARL provides the client with the results. If a sterility test is ordered, a Microbiology Report is issued, which they also refer to as a Certificate of Sterility. These reports certified the testing results were performed according to USP <71> standards.

After three days of testing, ARL would send a "preliminary" Microbiology Report which would classify the sample as "sterile" if no growth had occurred. If there was no growth after 14 days, ARL would certify the results as "final." Per USP guidelines, any sample that displayed turbidity during the testing period would be incubated for an additional four days, for a total of 18 days. ARL did not provide customers with an updated "final" 18 day report unless the sample became turbid (indicating growth of bacteria or fungal organisms) during the additional four days.

ARL was aware that NECC would use ARL's Microbiology Reports and other Certificates of Analysis as a way to advertise to customers and potential customers that it was compounding safe and sterile medications according to USP <797> and USP <71> standards.

3. Cleanroom and Equipment

As indicated above, cleanroom 1 was built by Liberty in 2006 for Ameridose. The space apparently underwent some minor renovations before NECC moved in in June 2011. NECC utilized powder containment hoods, laminar flow hoods, and barrier

isolator hoods. The hoods were state-of-the-art equipment. Scientific Air Analysis certified both the cleanroom itself and the hoods on a biannual basis. Issues with hoods and HEPA filters were dealt with promptly. The main cleanroom was an ISO 6 space with a HEPA filtration system that provided an ample air supply. Likewise, NECC's autoclave appears to have undergone preventative maintenance and calibration by Alert Scientific on a yearly basis. NECC's standard operating procedures also detail a comprehensive environmental monitoring program designed to ensure the cleanliness of the facility.

c. Institution of "the Calendar"

In early 2012, NECC, via Barry Cadden and Robert Ronzio (NECC's director of sales), instituted what was known as "the calendar," which governed when and how much compounded product would be produced at NECC. Prior to the calendar, compounding technicians simply compounded "stock" product on an as-needed basis when their supply began to get low. The calendar set a schedule for the compounding of certain products (including quantities) to be compounded on a monthly basis. Aside from creating a set schedule for compounding medications, the calendar significantly increased the amount of medications compounded at NECC each month, as much as ten-fold for some medications.

d. Compounding of Three Contaminated Lots

Three lots of methylprednisolone acetate compounded by NECC are associated with the fungal meningitis outbreak:

1. Lot 05212012@68 – Compounded on May 21, 2012
2. Lot 06292012@26 – Compounded on June 29, 2012

3. Lot 08102012@51 – Compounded on August 10, 2012.

My understanding of the process used in compounding these three lots is as follows:

1. Cory Fletcher weighed base-b, sodium phosphate monobasic, sodium phosphate dibasic, sodium chloride, polysorbate-80, and methylprednisolone acetate in a powder hood

2. Mr. Fletcher mixed the base-b, sodium phosphate monobasic, sodium phosphate dibasic, sodium chloride, and polysorbate-80 into sterile water (pre-filtered through a 0.22 micron Nalgene filter) in a glass beaker using a magnetic stir bar (autoclaved by NECC) on a mixing plate in Mr. Fletcher's workspace in the main room of cleanroom 1

3. Mr. Fletcher mixed the powdered methylprednisolone acetate into the solution using the stir bar and mixing plate, still on the table in cleanroom 1

4. Mr. Chin then homogenized the suspension in an isolator hood in cleanroom 1

5. Mr. Chin or Mr. Fletcher added sterile water to bring the suspension to final volume

6. Mr. Chin or Mr. Fletcher wrapped the beaker containing the suspension in multiple layers of foil, sealed it with autoclave indicator tape, and autoclaved it using the floor autoclave in one of the anterooms of cleanroom 1 at 121℃ and 15 PSI for approximately 15 minutes

7. Mr. Chin returned the suspension to the isolator hood for homogenizing

8. Mr. Chin or Mr. Fletcher used a Baxa repeater pump in an isolator hood to fill two 5 mL vials that were sent to ARL for testing

9. Mr. Fletcher transferred the suspension to pre-sterilized Nalgene bottles in an isolator hood

10. The Nalgene bottles were placed on a shelf in the main cleanroom to await processing

11. Owen Finnegan and Steven Haynes used a Baxa repeater pump in an isolator hood to fill sterile vials, as needed to fill orders shown on the compounder

12. Mr. Finnegan and Mr. Haynes stoppered the vials using sterile stoppers (autoclaved at NECC) in the isolator hood

13. Mr. Finnegan and Mr. Haynes capped and crimped the vials using a Cozzoli machine in an ISO 7 anteroom of cleanroom 1

14. Capped and crimped vials were sent out to the warehouse area for labeling and packaging before being shipped to customers, including STOPNC.

a. Testing of the Three Contaminated Lots

ARL tested two 5 mL vials from each of the three contaminated lots. From these two vials, one was used for the sterility test and one was used for the endotoxin and potency test. ARL used 1 mL of MPA to perform the sterility test. It incubated samples in the Tryptic Soy Broth ("TSB") growth media at 30° C. Below is a brief summary of the testing for each lot.

Lot 05212012@68 received by ARL on May 22, 2012		
	Result	Date
Preliminary	Sterile	May 25, 2012
Final	Sterile	June 5, 2012
Turbidity	None noted on final report	June 5, 2012

Lot 06292012@26 received by ARL on July 3, 2012		
	Result	Date
Preliminary	Sterile	July 6, 2012
Final	Sterile	July 17, 2012
Turbidity	Presumed Sterile[1]	July 21, 2012

[1] No report exists to confirm this sample was sterile at 18 days. If the additional incubation following the finding of turbidity found the sample to be non-sterile, there would likely be a report.

Lot 08102012@51 received by ARL on August 14, 2012		
	Result	Date
Preliminary	No Growth at 3 Days	August 17, 2012
Final	No Growth at 14 Days	August 28, 2012
Turbidity	Presumed No Growth at 18 Days[2]	September 1, 2012

b. 2012 Outbreak of Meningitis

In the fall of 2012, public health officials in Tennessee were alerted to a case of fungal meningitis caused by *Aspergillus fumigatus*. The source of the contamination was eventually traced back to the three contaminated lots of MPA compounded by NECC. The majority of cases with confirmed findings of fungus were found to have *Exserohilum rostratum*, rather than *Aspergillus fumigatus*.

c. Government Actions

In late September and early October 2012, the FDA and Massachusetts Board of Pharmacy conducted an exhaustive investigation of NECC's facility and compounding process. The FDA released a Form 483 from the investigation, and the Mass. BoP released a Preliminary Investigation Report. After a little over two years developing the case, the United States Attorney's Office indicted (1) the majority of NECC's owners, (2) virtually every pharmacist employed at NECC, and (3) one pharmacy technician.

Additionally, the FDA inspected ARL in November 2012 and issued a separate Form 483 summarizing its findings.

[2] No report exists to confirm this sample was sterile at 18 days. If the additional incubation following the finding of turbidity found the sample to be non-sterile, there would likely be a report.

IV. Opinions

a. Summary

In my opinion and to a reasonable degree of scientific probability, NECC, UniFirst, and/or ARL violated the acceptable standard of professional practice and caused the Plaintiffs' injuries. NECC failed to properly maintain its facility and properly perform environmental monitoring, and failed to take remedial action when environmental sampling indicated contamination within the cleanroom, as required by USP <797> and the standard of care. NECC and UniFirst failed to properly clean NECC's facility, in accordance with USP <797> and the standard of care. And, NECC's compounding process for the MPA was flawed and violated USP <797> and the standard of care. Finally, NECC and ARL failed to properly test the three contaminated lots in compliance with USP <797>, USP <71>, and the standard of care.

Furthermore, NECC, in violation of the standard of care, made numerous misrepresentations to customers regarding (1) the quality of its products, (2) its compliance with USP <797> and USP <71>, and (3) the results of NECC's environmental monitoring and product testing programs. In my opinion, it was reasonable for STOPNC to accept representations from NECC as true, and I would not expect a nurse-administrator (like Ms. Schamberg) or an anesthesiologist (like Dr. Culclasure) to be familiar with the technical aspects of medication compounding. It was reasonable for them to believe, based on the fact that NECC was permitted to operate, that either the FDA, the Tennessee Board of Pharmacy, or the Massachusetts' Board of Pharmacy was overseeing NECC's activities to ensure that NECC was acting properly in compounding and selling medications across the country and in Tennessee.

Finally, in my opinion, prior to the outbreak, there was no general belief in the pharmacy or medical community that compounded medications were inherently unsafe or dangerous, warranting heightened due diligence before purchasing from a compounding company. In my experience, customers rarely, if ever, conducted the due diligence the Plaintiffs' allege was required; it certainly was not the standard of care to do so, in my opinion.

a. USP <797>, USP <71>, and USP <85>

USP <797> is a set of comprehensive guidelines for sterile compounding. USP <797> contains specific criteria and instructions for cleaning and maintaining a cleanroom, the actual compounding process, and medication testing, by reference to USP <71> and USP <85>, which provides more specific instructions for medication testing. NECC was required to comply with all USP standards when compounding the MPA at issue.

b. Facility Cleaning and Upkeep

NECC's facility seems to have been poorly maintained, cleaned, and monitored.

i. Cleanroom Maintenance

One of the ways cleanroom control contamination is by ensuring that the cleanroom envelope is secure. This serves two purposes: (1) it prevents particles/contamination from entering the cleanroom through gaps in the envelope and (2) it helps maintain positive pressure. Positive pressure is designed to push air from areas designed to more stringent air quality standards to areas of lower air quality standards. This is intended to create a constant air flow to less "clean" areas that helps prevent contamination from entering the cleaner areas of the cleanroom. When the

cleanroom envelope is insecure, air escapes, reducing the positive air pressure and the attendant safeguarding effect, making contamination of the cleanroom more likely.

Cleanroom 1's envelope had several issues that compromised its security. First, the ceiling had gaps that would have permitted particles to enter the main cleanroom area. Second, many of the door seals and floor sweeps were damaged and needed to be replaced. Third, there were multiple punctures to the cleanroom wall, such as for electrical wiring, plumbing, and sprinklers, that were not properly sealed. Finally, NECC utilized a wall pass-through using plastic flaps, rather than a pass through with some sort of door. All of these issues would have reduced the overall positive pressure of the room and would have been a location where contamination could have entered the cleanroom. In my opinion, these problems more probably than not created conditions in NECC's facility that made contamination more likely, and should have been remedied by NECC.

ii. Cleanroom Cleaning

In my opinion, NECC's facility was not properly cleaned which contributed to the conditions that lead to the contamination of the three contaminated lots. USP <797> contains strict guidelines for cleanroom cleaning. USP <797> requires daily and monthly cleaning. Daily cleaning is required for floors, counter tops and other easily cleaned horizontal areas. USP <797> stipulates the use of disinfectant cleaning solutions with sporicidal activity. Residue from disinfectants is to be removed with sterile 70% isopropyl alcohol.

While I understand that NECC's pharmacy technicians say that the facility was always cleaned as required by USP <797>, the fact that documentation was not

completed contemporaneously with the cleaning calls this into question. The purpose of the documentation is to allow a historical review of the cleaning that was performed to confirm that it was done as required, when required, and to identify the person who completed the cleaning. It was a violation of the standard of care for Mr. Chin to instruct pharmacy technicians in cleanroom 1 to complete cleaning logs at the end of the month even if the technicians had not personally completed the cleaning tasks.

I will note that the testimony in this case leads me to believe that the cleanroom actually *appeared* clean. However, viable particles, which can lead to contamination, are usually microscopic. Thus, the simple fact that NECC's cleanroom appeared clean to the naked eye does not mean that it was in fact clean. One of the purposes of environmental monitoring is to monitor the true cleanliness of the cleanroom. In fact environmental sampling records indicated microbial growth was being captured during air and surface sampling done at the facility, yet no remedial action appears to have been taken to identify or eliminate the source of the contamination.

Additionally, it is eminently clear that the monthly cleaning by UniFirst's cleaning technicians was *not* in compliance with USP <797>, NECC's standard operating procedures, or UniFirst's standard operating procedures. UniFirst's cleanroom technicians departed from the standard of care in the following material respects:

1. Failing to properly garb up before entering the cleanroom
2. Failing to properly use UniFirst's "Mop King" system when mopping cleanroom floors
3. Failing to use the proper mopping technique when cleaning the cleanrooms

4. Failing to properly change tacky mats.

In my opinion, these failures likely contributed to the conditions in cleanroom 1 that led to the contamination. More importantly, on at least two occasions in 2012, NECC's environmental monitoring program identified fungus in NECC's cleanrooms on the same day that UniFirst's cleaning crew was in the facility, indicating a link between UniFirst's technicians and the worsening conditions in NECC's cleanroom.

To make matters worse, UniFirst (and NECC) failed to take appropriate steps to eliminate the fungal contamination. UniFirst did not regularly rotate a sporicidal agent in the cleaning process. This is particularly problematic because, based on the documents I have reviewed, UniFirst was solely responsible for cleaning the walls and ceilings at NECC. Thus, UniFirst should have known that if they were not cleaning the walls and ceilings with a sporicidal agent, it was not being done at all.

In my opinion, UniFirst's cleaning practices fell below the standard of care and more likely than not contributed to the conditions in NECC's facility that caused the contamination.

iii. Environmental Monitoring

NECC's failure to properly employ an environmental monitoring program violated USP <797> and the acceptable standard of care. In my opinion, NECC's failure to comply with USP <797> and its own internal procedures regarding environmental monitoring contributed to cause the outbreak.

At the outset, I must acknowledge that my review of the actual environmental monitoring records has been limited. My understanding is that some of the records were either not provided by NECC or were seized by the government. However, the

Form 483 issued by the FDA regarding its investigation of NECC provides ample information upon which I can rely.

The Form 483 shows that NECC had *numerous* instances of alert or action levels in 2012 from its environmental monitoring program. Many of these instances involved alert or action levels for mold around the same time as the compounding the three contaminated lots, including action levels for mold in cleanroom 1 on the day before the 06292012@26 lot was compounded. Notwithstanding these alert and action levels, it appears that NECC took no steps to identify the source of the mold and bacteria and took no corrective action. This violates USP <797>, NECC's internal standard operating procedures, and, in my opinion, contributed to cause the outbreak. In my opinion, had NECC taken steps to identify and eliminate the source of the cleanroom contamination identified by the environmental monitoring program when it occurred, the outbreak is less likely to have occurred.[3]

c. Compounding Process

In my opinion, NECC's compounding process violated the standard of care contributed to cause the contamination in two ways: (1) NECC's institution of "the calendar" pushed NECC beyond its capacity to safely compound medication and (2) the actual process used to compound MPA violated USP <797>.

i. The Calendar

As explained above, NECC significantly increased production in early to mid-2012. In my opinion, this production increase likely created a strain on NECC's compounding personnel and led to mistakes during the compounding process. I

[3] For example, NECC could have used a hydrogen peroxide fogging system to decontaminate the cleanroom.

understand that, when NECC began to increase production, Joseph Connolly expressed this precise concern to Glenn Chin, and, in response, Mr. Chin shrugged, rather than taking steps to remedy the issue.

In my experience, the increased strain on compounding personnel caused by the increased production demands probably led to mistakes. I believe that one manifestation of this problem is the falsification of the cleaning logs. In my opinion, NECC's compounding personnel were probably too busy to complete the cleaning logs when cleaning actually occurred, due to the increased workload created by "the calendar." Another example is the production of sub-potent eye blocks in early 2012 that were provided to Massachusetts Eye and Ear Institute.

In my opinion, the institution of "the calendar" made mistakes in the compounding process more likely and, more probably than not, contributed to cause the outbreak.

ii. Compounding of Three Contaminated Lots

In my opinion, NECC's compounding process for the three contaminated lots departed from USP <797> and the standard of care because NECC (1) failed to autoclave the MPA for 20 minutes, and (2) autoclaved the bulk suspension, rather than employing terminal sterilization. USP <797> requires terminal sterilization by autoclaving for a minimum of 20 minutes at 121℃ and 15 PSI.

Based on NECC's compounding process, I believe that the most likely point of contamination was when the MPA was being compounded in the main cleanroom on a table which served as Mr. Fletcher's workspace (*i.e.*, when the ingredients were being mixed). I believe this is far more likely than contamination occurring in a glove box, where the rest of the compounding process occurred. As discussed at length above,

there were numerous conditions in the cleanroom that made contamination more likely. However, there is no indication that there were any problems with the isolator hoods that would have permitted the contamination in the main cleanroom to enter the isolator hood. Additionally, the isolator hoods are ISO-5 spaces, and are, by design, cleaner work areas than the cleanroom itself, which was an ISO-6 space. To be clear, it was permissible under USP <797> for the MPA to be mixed/compounded in Mr. Fletcher's work space in the main cleanroom because the MPA was going to be sterilized by autoclaving later.

According to the indictment, the three contaminated lots were autoclaved at 121℃ and 15 PSI, as follows:

Lot 05212012@68 – 15 minutes and 4 seconds

Lot 06292012@26 – 15 minutes and 5 seconds

Lot 08102012@51 – 15 minutes and 4 seconds.

This does not comply with USP <797> or the standard of care. I believe that the autoclaving process failed to eliminate the fungal contamination that occurred earlier in the compounding process. I should note that NECC's standard operating procedures only required autoclaving for 15 minutes. However, USP <797> clearly states that 20 minutes, *minimum*, was required.[4]

This practice also does not meet USP <797> standards because the final product was not sterilized. Even if this autoclaving did render the entire batch of product sterile, contamination could also occur during the filling and capping process. After this filling

[4] There is some suggestion in the documents that NECC failed to properly validate the autoclave to ensure that it was properly functioning to eliminate contamination. I have not seen sufficient information on this issue to form an opinion.

process is when the sterilization should have occurred, thus the use of the word "terminal sterilization". Since NECC was neither terminally sterilizing the final dispensing unit nor testing the final dispensing units, this contamination would not be detected.

The correct procedure would have been to compound the steroid injection, package it within six (6) hours of being prepared, then terminally sterilize the containers using steam under pressure (autoclave) for a sufficient period of time to render the individual vials of steroid injection sterile.

In my opinion, NECC's failure to properly terminally sterilize the MPA for the required 20 minutes more likely than not contributed to cause the outbreak.

d. Testing of Three Contaminated Lots

In my opinion, NECC and ARL's departure from USP <797>, USP <71>, and the standard of care as it relates to sterility testing contributed to cause the outbreak.

The practice at NECC was to prepare a batch of an injectable medication that was about 12,500 mL. From this single, large container of 12,500 mL, only 10 mL was removed for sterility testing. At some time in the future, presumably after a test result was obtained, the 4,500 mL batch was transferred to 1 and 5 mL containers for dispensing. This failed to comply with the sterility testing requirements of USP <797>, USP <71>, and NECC's own standard operating procedures in three ways.

First, NECC failed to submit the minimum number of articles to be tested in relation to the number of articles in the batch as outlined in USP <71>. NECC staff members were responsible for sending a representative sample size to comply with USP <71> to the testing lab. All three contaminated lots contained well over 500 vials. Per USP <71> Table 3, an appropriate sample size would have been no fewer than 20

containers of the steroid injection, but NECC only submitted two 5 mL vials for testing for each lot.

Second, testing should have been performed on the final product to ensure sterility, using USP <71> compliant testing procedures. While USP <797> only "recommends" that test samples be finished preparations, NECC's own standard operating procedures (and the standard of care) required it. NECC knew or should have known that test results for samples drawn from a bulk preparation do not accurately reflect the sterility of the finished compounded sterile preparation to be sold to a client.

Third, NECC violated USP <797> standards by releasing MPA to customers before ARL had finalized the results of the sterility tests for Lot 06292012@26 and Lot 08102012@51. Sterility testing takes 14 days at minimum under the USP standards.

ARL began the sterility test for Lot 06292012@26 on July 3, 2012. This lot demonstrated turbidity and required an additional four days of testing. NECC shipped MPA from this lot to Tennessee[5] on July 16, 2012, one day before the conclusion of the standard 14-day testing period and five days before the result of the sterility test was finalized due to the presence of turbidity.

Sterility testing for Lot 08102012@51 began on August 14, 2012. This lot also required an additional four days of testing due to turbidity. NECC shipped one order of MPA from this lot to Tennessee[6] on August 21, 2012, seven days before the conclusion of the standard 14-day testing period and 11 days before the result of the sterility test was finalized due to the presence of turbidity. NECC shipped another order from this lot on August 31, 2012, one day before the sterility test was finalized.

[5] This shipment was sent to Specialty Surgery Center in Crossville, Tennessee.
[6] This shipment was sent to PCA Pain Care Center in Oak Ridge, Tennessee.

NECC repeatedly ignored the requirements of USP <797> and its own standard operating procedures. In my opinion, had NECC submitted the minimum number of articles from the compounded batch as outlined by USP <71> and had the submitted samples been drawn from the final preparation, rather than the bulk preparation, any fungus present in the contaminated lots would have been discovered by the sterility test. In addition, although NECC did not cause the contamination by releasing MPA before the sterility tests were finalized, this action increased the risk of a widespread outbreak and is yet another example of NECC's systematic failure to comply with the sterile compounding guidelines of USP <797>.

In my opinion, ARL's testing procedures and improper citation to USP <71> on its Microbiology Reports and Certificates of Analysis departed from the USP <797> standards and the standard of care, and contributed to the meningitis outbreak. Despite only testing two 5 mL vials, ARL certified all three contaminated lots as sterile *under USP <71>*. ARL was not only aware of that customers were sending fewer than the required number of samples, but it made no effort to obtain additional vials from NECC in order to comply with USP <71>. ARL also ignored the quantity of the sample that was required to be used for the sterility test. Although it received two 5 mL vials of MPA from each contaminated lot, it only used 1 mL from one vial to perform the sterility test. To perform the sterility test in compliance with USP <71>, at least 2.5 mL from each container should have been used.

Finally, ARL's representative admitted during his deposition that the incubation temperature ARL used for the TSB media exceeded the maximum USP <71> guideline of 25°C. ARL incubated the TSB media at 30°C.

ARL violated the standard of care when it provided clients with Microbiology Reports and Certificate of Analysis that certified samples as sterile under USP <71> even though it knew that its testing protocols and procedures did not meet this standard. Furthermore, ARL knew that NECC could use those reports and their reference to USP <71> to market its products as being sterile and safe.

It is my opinion that had ARL adhered to USP <71> standards for sterility testing, any fungus contained in the MPA produced by NECC would have been discovered. Additionally, ARL's improper citation to USP <71> on its Microbiology Reports and Certificates of Analysis prevented NECC's clients from understanding the true nature of the medication they purchased. Had NECC and ARL adhered to the USP <797> and USP <71> standards as they claimed, the contamination would more likely than not have been discovered, and this outbreak would have been avoided.

* * * * * * * *

Thus, NECC failed in four fundamental ways with the production of compounded steroid injection:

a. failure to terminally sterilize the drug in its final container

b. failure to sterilize the container of drug for sufficient amount of time

c. failure to submit a sufficient number of samples to the testing lab

d. failure to submit samples of the "final" product for testing.

In my opinion, these failures violated the standard of care and more likely than not contributed to cause the outbreak.

e. Representations to Customers

NECC represented to customers, through its salesforce employed by Medical Sales Management, made the following representations to customers, including STOPNC, that:

- NECC was USP <797> compliant
- NECC had a comprehensive end-product testing program
- NECC had a strictly-enforced environmental monitoring program.

As outlined in detail above, none of the above was true. Obviously, it was a violation of the standard of care for NECC to lie to its customers.

Additionally, I would not expect Ms. Schamberg or Dr. Culclasure (or most other nurses or anesthesiologists) to be sufficiently well-versed in the technical aspects of medication compounding to recognize these misrepresentations. Many *pharmacists* who purchased from NECC were likewise duped. In fact, the evidence indicates that even if STOPNC had inquired further into NECC's environmental monitoring and end-product testing program, NECC would have provided "Quality Assurance Report Cards" with falsified or misleading information designed to assure customers of the safety and quality of NECC's compounding process.

In my opinion, it is completely reasonable for a customer of a compounding pharmacy to believe what the compounding pharmacy's representatives say. Further, in my opinion, it was reasonable for NECC's customers to rely on the regulatory agencies responsible for overseeing the making of drugs in the United States (the FDA and state boards of pharmacy) to ensure that NECC was acting appropriately and complying with appropriate industry laws, regulations, and guidelines.

f. Use of Compounded Medications and Customer Diligence

Prior to the fungal meningitis outbreak, there was no generally-held belief in the medical or pharmaceutical community that compounded medications were inherently dangerous or unsafe, warranting additional scrutiny. Regardless, if that were the case, the additional scrutiny should have come from the FDA and state boards of pharmacy, not individual health care providers who purchased the medication. If compounded medications were risky or dangerous, the FDA and state boards of pharmacy would not have permitted them to operate.

I understand that the Plaintiffs' allege that STOPNC (and NECC's thousands of other customers) were required by the standard of care to conduct the following due diligence prior to purchasing from NECC:

- Travel to Massachusetts to perform an on-site inspection of NECC's facility
- Evaluate NECC's standard operating procedures
- Evaluate NECC's pharmacist training
- Evaluate examples of "quality-control reports"
- Evaluate NECC's environmental monitoring program
- Evaluate NECC's end-product testing program
- Determine whether NECC was accredited
- Determine whether NECC had ever been sued for a compounded product
- Contact the FDA and the Massachusetts Board of Pharmacy to determine whether NECC had any regulatory issues
- Evaluate history of the results of *all* NECC accreditation or regulatory surveys conducted of NECC's facility.

None of the above was standard practice prior to the fungal meningitis outbreak. While I cannot speak to this issue from the standpoint of a *purchaser* of compounded medication, I can speak to it from the perspective of a *seller* of compounded medication, and the simple fact is that the vast majority of my customers did none of the above before purchasing from me, prior to the fungal meningitis outbreak. Thus, in my opinion, this heightened "due diligence" was not required by the standard of care applicable to STOPNC.

V. List of Cases

The following is a list of all other cases in which I have testified as an expert at trial or by deposition in the past four (4) years:

Ferguson v. Brasco, CV12-900148 (Circuit Court for Madison County, AL)

VI. Publications

My *curriculum vitae* contains a list of my publications over the last ten years.[7]

VII. Compensation

I am being compensated $250/hour for my time on this case. My compensation is in no way contingent upon the outcome of the case.

WILLIAM MIXON, RPH MS, FIACP

January 15, 2016
DATE

[7] Attached as Exhibit 2.

EXHIBIT 1

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[3]LICENSED IN TN & GA
[4]LICENSED IN TN & KY
[5]LICENSED IN TN & WI

Matthew H. Cline
Matt@gideoncooper.com

December 31, 2015

Mr. William Mixon, RPh, MS FIACP
The Compounding Pharmacy
750 Fourth Street, Southwest
Hickory, NC 28602

RE: NECC Meningitis Litigation – Expert Review of Purchase Decision

Dear Mr. Mixon:

In Tennessee, pursuant to the "locality rule," an expert witness must have a "modicum of familiarity" with the medical community in which the defendant provider practices or a similar community. In order to demonstrate that requisite "modicum of familiarity," the expert need not have direct, firsthand knowledge of the community and may, instead, educate himself by various means, including by reviewing reference materials on pertinent statistical information, such as community size, the number and types of medical facilities in the area. The expert may also familiarize himself with the community by visiting the community and/or conversing with medical providers in the community.

This letter provides you some background information on the medical communities at issue, to the extent you need it to become familiar (or more familiar) with the medical communities at issue. You need not memorize this information. You should simply review it and use it generally in your overall consideration of the appropriateness of the actions by the medical providers in these cases.

Here, the communities at issue are Nashville, Davidson County, Tennessee, where STOPNC is located, and Crossville, Cumberland County, Tennessee, where Specialty Surgery Center of Crossville was located. I have provided information below on each of these communities in order to assist you in familiarizing yourself with them.

Davidson County, Tennessee

- Population: 626,681(2010); 668,347 (2014).[1]
- Racial Makeup: 56.9% white; 28.1% black; 0.5% American Indian/Alaska Native; 3.4% Asian; 9.9% Hispanic/Latino (2014).[2]
- Education: 86.4% high school graduate or higher; 35.9% Bachelor's degree or higher (2009-2013).[3]
- Median income: $47,335 (2009-2013).[4]
- Persons below poverty level: 18.5% (2009-2013).[5]
- Hospitals: 13.[6&7]
- Ambulatory Surgical Treatment Centers: 30.[8&9]

Cumberland County, Tennessee

- Population: 56,053 (2010); 57,985 (2014).[10]
- Racial Makeup: 94.9% white; 0.7% black; 0.4% American Indian/Alaska Native; 0.5% Asian; 2.7% Hispanic/Latino (2014).[11]
- Education: 80.9% high school graduate or higher; 17.4% Bachelor's degree or higher (2009-2013).[12]
- Median income: $37,188 (2009-2013).[13]

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[1] *See* Census Quickfacts for Davidson County (attached).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.*
[6] *See* TN Dept. of Health website for Davidson County Hospitals (complete list attached). This information can also be located through the TN Dept. of Health's searchable database of health care facilities, at https://apps.health.tn.gov/Facilities_Listings/facilities.htm.
[7] Nashville, as you know, is a large medical community. It has multiple hospitals with virtually all specialties represented. It has a large academic medical center (Vanderbilt University Medical Center), and several large, urban hospitals, plus several large hospitals in the metropolitan area.
[8] *See* TN Dept. of Health website for Davidson County Ambulatory Surgical Treatment Centers (complete list attached).
[9] STOPNC is a Joint Commission accredited, free-standing ambulatory surgical center affiliated with Howell Allen Clinic, a Nashville-based neurosurgical group. Since 2005, STOPNC has focused exclusively on pain management, with epidural steroid injections (ESI's) accounting for almost all of the procedures performed there. STOPNC has two operating rooms and a procedure room, all of which were utilized for the performance of ESI's. At the time of the care at issue in these lawsuits, the ESI's were performed primarily by John Culclasure, M.D., the Medical Director, who performed procedures four days of the week, and a second physician, who performed procedures two days of the week. The physicians were assisted by a staff of nurses.
[10] *See* Census Quickfacts for Cumberland County (attached).
[11] *Id.*
[12] *Id.*
[13] *Id.*

- Persons below poverty level: 17.6% (2009-2013).[14]
- Hospitals: 1.[15&16]
- Ambulatory Surgical Treatment Centers: 3.[1718]

Please consider this information in your review to ensure that you have a basic understanding of the medical communities at issue and, if you have any questions, do not hesitate to call me.

Sincerely,

/s/ Matthew H. Cline

Matthew H. Cline

MHC/gfw

[14] *Id.*

[15] *See* TN Dept. of Health website for Cumberland County Hospitals (complete list attached).

[16] The only hospital in Cumberland County is Cumberland Medical Center, a 189 bed facility in Crossville, Tennessee with an ER, ICU, and labor & delivery unit. Specialties represented on staff include family practice, pediatrics, internal medicine, cardiology, neurology, general surgery, obstetrics and gynecology, orthopedics, gastroenterology, pathology, radiology, and anesthesiology.

[17] *See* TN Dept. of Health website for Cumberland County Ambulatory Surgical Treatment Centers (complete list attached). Notably, at the time of the care provided, SSC was also an active surgical center in Cumberland County, bringing the total to three. SSC was sold to Cumberland Medical Center in 2013.

[18] SSC was a free-standing ambulatory surgical center that was purchased by Cumberland Medical Center in 2013. SSC had two operating rooms and a procedure room, and procedures were performed by several specialties at SSC, including endoscopy, general surgery, orthopedics, and pain management. Pain management procedures were performed by Kenneth Lister, M.D. and included ESI's, facet injections, and sacroiliac injections. Dr. Lister performed approximately 20-30 procedures per week, approximately half of which were ESI's.

EXHIBIT 2

William Mixon, RPh, MS, FIACP, FACA
The Compounding Pharmacy
750 Fourth Street, Southwest
Hickory, NC 28602
Tel: 828-324-4115 • Fax: 828-322-7299
wmixon@thecompoundingrx.com

Owner-manager, The Compounding Pharmacy, Hickory, North Carolina; a Pharmacy Compounding Accreditation Board (PCAB)-accredited compounding-only pharmacy, September 2007 – present

Education/academic preparation

Master of Science degree, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 1983

Residency, hospital pharmacy, North Carolina Memorial Hospital, Chapel Hill, North Carolina, 1981 – 1983

Residency, hospital pharmacy, Spartanburg General Hospital, Spartanburg, South Carolina, 1980 – 1981

Bachelor of Science degree in Pharmacy, Medical University of South Carolina, Charleston, South Carolina, 1977

Prepharmacy training, Coker College, Hartsville, South Carolina, 1972 – 1974

Pharmaceutical compounding specialties

Sterile and nonsterile compounds, autologous serum eye drops, veterinary and human chemotherapy

Academic appointments

Adjunct assistant professor, Division of Practice Advancement and Clinical Education , University of North Carolina Eshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 2010 – 2015

Clinical associate professor of pharmacy practice, Wingate University School of Pharmacy, Wingate, North Carolina, 2006 – present

Preceptor, University of North Carolina School of Pharmacy, Chapel Hill, North Carolina, 1998 – present

Preceptor, Campbell University College of Pharmacy and Health Sciences, Buies Creek, North Carolina, 2004 – present

Professional services and consultation

503B Outsourcing facility pharmacist consultant, Exela Pharma Sciences, LLC, Lenoir, North Carolina

Senior associate, Gates Healthcare Association, Middleton, Massachusetts

Pharmacist manager, Burke County Health Department, Morganton, North Carolina

Professional memberships and appointments

Member, Board of Pharmacy Specialties Sterile Compounding Role Delineation Study Taskforce, October, 2015

Member, United States Pharmacopeial Compounding Expert Committee, 2015 – 2020 cycle

Compounding special interest group coordinator-elect, American Pharmacists Association-Academy of Pharmacy Practice and Management, 2015 – 2016

President, North Carolina Board of Pharmacy, 2015

Chairman, Catawba County Board of Health, 2014 – 2015

Member, United States Pharmacopeial Compounding Expert Committee, 2010 – 2015 cycle

Member, Chapter 800 Subcommittee of the United States Pharmacopeial Convention Expert Committee for Compounding, 2010 – 2015 cycle

Member, Chapter 797 Subcommittee of the United States Pharmacopeial Convention Expert Committee for Compounding, 2010 – 2015 cycle

Industry representative, Pharmacy Compounding Advisory Committee of the United States Food and Drug Administration

Member, Expert Committee of the United States Pharmacopeial Convention Good Distribution Practices Expert Panel

American Pharmacists Association nominee, Pharmacy Compounding Advisory Committee of the United States Food and Drug Administration

Fellow, American College of Apothecaries

Member, American College of Veterinary Pharmacists

Member, American Society for Pharmacy Law

Fellow, International Academy of Compounding Pharmacists

Member, American Pharmacists Association

Member, National Community Pharmacists Association

Member, Professional Compounding Centers of America

Member, North Carolina Association of Pharmacists

Certification

Certification in geriatric pharmacy, Commission for Certification in Geriatric Pharmacy, Alexandria, Virginia, 2001 – 2006

Certification in pharmacy-based immunization delivery, University of North Carolina at Charlotte, Charlotte, North Carolina, 2005

Certification in diabetes education, National Certification Board for Diabetes Educators, Arlington Heights, Illinois, 1999 – 2004

Licensure

Licensure by reciprocity, North Carolina Board of Pharmacy, 1981

Licensure by examination, South Carolina Board of Pharmacy, 1977

Licensure by reciprocity, Virginia Board of Pharmacy, 2012

Licensure by reciprocity, Tennessee Board of Pharmacy, 2012

Pharmacy accreditation

Pharmacy Compounding Accreditation Board, 2007 – present

Publications

Pritchett J, Mixon B. Performance improvement in compounding pharmacy: A template for assessment, implementation, and sustained success. *IJPC*. In press.

Mixon B. What will happen to repackaged Avastin for use by ophthalmologists when the FDA draft guidance on mixing, diluting, or repackaging biological products outside the scope of an approved biologics license application becomes official policy? Pharmacy OneSource Web site. In press.

Mixon B, Mixon J, Isbey III EK et al. Autologous serum eye drops for severe dry eye syndrome in a patient with chronic graft-versus-host disease: A case report. *IJPC* 2014; 18(5): 370-377.

Helms R, Fox S, Mixon W et al. Compounded pimobendan for canine chronic degenerative mitral valve disease and pulmonary hypertension. *IJPC* 2012; 16(1): 34-41.

Mixon W, Fox S, Barnes D et al. Quality control: Undecided about buying an in-house water purification system? Pros, cons, and caveats that may provide the answers you need. *IJPC* 2011; 15(6): 480-487.

Mixon B, Wood AP, Low J, et al. Waterless alcohol-based hand sanitizers for the compounding pharmacy. *IJPC* 2011; 15(4): 278-284.

Williams A, Mixon W. Prophylaxis against exposure to bloodborne pathogens during compounding. *IJPC* 2010; 14(1): 14-18.

Mixon W, Angelle P, Chang RI. Autologous eye drops for the treatment of dry eye and neurotrophic keratitis. *IJPC* 2009; 13(6): 506-515.

Mixon W, Ille G. Preventing nonmicrobiologic airborne contamination in the compounding pharmacy: Ensuring a safe environment for compounders, staff, and clients. *IJPC* 2009; 13(4): 290-294.

Mixon W, Huffman L. Tips for cleanroom construction and renovation. *IJPC* 2009; 13(2): 100-104.

Mixon W, Angelle P, Yoch D. Compounding for pediatric patients: Case reports and formulations. *IJPC* 2009; 13(1): 6-12.

Mixon W, Northrup N, Vail J. Compounding for cancer in companion animals. *IJPC* 2009; 13(1): 42-49.

Mixon W, Helms SR. Transdermal amlodipine besylate in Lipoderm for the treatment of feline hypertension: A report of two cases. *IJPC* 2008; 12(5): 392-397.

Mixon W, Cabaleiro J, Latta KS, et al. Microbial air-sampling equipment, part 2: Experiences of compounding pharmacists. *IJPC* 2008; 12(4): 321-327.

Presentations

Mixon B. The Drug Quality and Security Act — HR 3204 — Where are we today? Presented at the IACP Compounders on Capitol Hill annual meeting; June 2015; Washington, DC.

Mixon W. *USP* 800: Let's plan ahead. Presented at the American College of Veterinary Pharmacists Webinar; January 2015; Hickory, North Carolina.

Mixon W. Autologous serum eye drops. Presented at the American College of Apothecaries specialty conference; October 2014; Baltimore, Maryland.

Mixon W. Proposed *USP* Chapter 800. Presented at the Pharmacists Society of the State of New York annual convention; June 2014; New York, New York.

Mixon W. Practice upgrade: You've decided to do sterile compounding, now what? Presented at the Professional Compounding Centers of America Concierge Congress; April 2011; Chicago, Illinois.

Mixon W. How to implement a staff incentive program at your pharmacy. Presented at the Professional Compounding Centers of America Compounding Pharmacy Management Services annual client meeting; October 2010; Houston, Texas.

Mixon W. Compounding in veterinary medicine. Presented at the Current Treatment Strategies in Veterinary Oncology Seminar, University of Georgia College of Veterinary Medicine; December 2007; Athens, Georgia.

Mixon W. Compounding for hospice patients. Presented at the Annual Meeting of the Carolinas Center for Hospice and Palliative Care; October 2003; Myrtle Beach, South Carolina.

Mixon W. Hypoglycemia, hyperglycemia, and new diabetic therapies. Presented at the Lenoir Living Center; February 2002; Lenoir, North Carolina.

Mixon W. Compounded medications for palliative care. Presented at the Professional Compounding Centers of America Regional Seminar; September 2000; Atlanta, Georgia.

Mixon W. Type 2 diabetes update. Presented at the Lenoir Living Center; October 1999; Lenoir, North Carolina.

Mixon W. Hypoglycemia treatment and awareness. Presented at the Certification Program in Diabetes Management, Charlotte Area Health Education Center; April 1999; Charlotte, North Carolina.

Grant submission

Implementation of a computerized version of the Micromedex Poisindex System (Thomson Reuters, Ann Arbor, Michigan) in a community-hospital–based poison information center. Submitted to the Kate B. Reynolds Foundation, 1989.

Awards and honors

Corecipient of the 2013 United States Pharmacopeial Convention Award for an Outstanding Contribution to the Standards-setting Process

Elected to the United States Pharmacopeia Council of Experts for Compounding, 2010

Recipient, on behalf of The Compounding Pharmacy, of the Faith in the Future Award from the Catawba County Chamber of Commerce, Hickory, North Carolina, 2008

Pharmacist of the Month, Professional Compounding Centers of America, August 2004

Rho Chi Pharmaceutical Honor Society, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, 1983

International travel

Germany, Scotland, England, Canada